Cefazolin PANPHARMA 1 g
Powder for solution for injection

1. NAME OF THE MEDICINAL PRODUCT

CEFAZOLIN PANPHARMA 1 G

Powder for solution for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Cefazolin (as sodium) 1 g

3. PHARMACEUTICAL FORM

Powder for I.M. or I.V. use.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Cefazolin is indicated for the treatment of infections due to susceptible organisms and also perioperatively for prophylaxis.

Treatment includes:

Respiratory tract infections due to *Streptococcus pneumoniae* (formerly *Diplococcus pneumoniae*), *Klebsiella* species, *Haemophilus influenza*, *Staphylococcus aureus* (penicillin-sensitive and penicillin-resistant) group A beta-haemolytic streptococci, streptococci of the nasopharynx.

Urinary tract infections due to *Escherichia coli*, *Klebsiella species*, *Proteus mirabilis* and some strains of *Enterobacter* and enterococci.

Skin and skin structure infections due to *Staphylococcus aureus* (penicillin-sensitive and penicillin-resistant), group A beta-haemolytic streptococci and other strains of streptococci.

Biliary tract infections due to *Escherichia coli*, various strains of streptococci, *Proteus mirabilis*, *Klebsiella* species and *Staphylococcus aureus*.

Bone and joint infections due to *Staphylococcus aureus*.

Genital infections due to *Escherichia coli*, *Proteus mirabilis*, *Klebsiella* species and some strains of streptococci.

Septicemia due to *Streptococcus pneumoniae* (formerly *Diplococcus pneumoniae*), *Proteus mirabilis*, *Escherichia coli* and *Klebsiella* species.

Endocarditis due to *Staphylococcus aureus* (penicillin-sensitive and penicillin-resistant) and group A beta-haemolytic streptococci.

Perioperative prophylaxis:

The prophylactic administration of cefazolin perioperatively (preoperatively, intraoperatively and postoperatively) may reduce the incidence of certain postoperative infections in patients undergoing surgical procedures (hysterectomy, gastrointestinal surgery) that are classified as contaminated or potentially contaminated.

The perioperative use of cefazolin may also be effective in surgical patients in whom infection at the operative site would present a serious risk (open-heart surgery and prosthetic arthroplasty).

4.2 Posology and method of administration

Cefazolin may be administered I.M. or I.V. after reconstitution; total daily dosage is the same for either route of administration (I.M. or I.V.).

Usual Adult Dosage:

Pneumococcal pneumonia: 0.5 g every 12 hours.

Mild infection caused by susceptible Gram-positive cocci: 250 mg to 500 mg every 8 hours.

Acute uncomplicated urinary tract infections: 1 g every 12 hours

Moderate to severe infections: 500 mg to 1 g every 6 to 8 hours

Severe, life-threatening infections (endocarditis, septicaemia): 1 g to 1.5 g every 6 hours

Maximum daily dose is up to 6 g; however, doses of up to 12 g have been prescribed in rare cases.

Dosage adjustments in renal failure (guidelines):

In patients with impaired renal function, the doses should be adjusted according to creatinine clearance or serum creatinine levels (see table).

After an initial loading dose:

CREATININE ml/min	SERUM CREATININE MG/100 ML	DOSAGE
≥ 55	≤ 1.5	Full dosage
35-54	1.6 to 3.0	Full dosage restricted to at least 8 hours intervals
11-34	3.1 to 4.5	½ of the usual dose every 12 hours
10 or less	4.6 or more	½ of the usual dose every 18 to 24 hours

Usual Children's Dosage:

In children, a total daily dosage of 25 mg to 50 mg/kg body weight, divided into 3 to 4 equal doses, is effective for most mild to moderately severe infections. Total daily dosage may be increased to 100 mg/kg body weight in severe infections.

Paediatric dosage guide:

Weight in kg	25 mg/kg/day divided in 3 doses (approx. single dose: mg/every 8 h)	25 mg/kg/day divided in 4 doses (approx. single dose: mg/every 6 h)
4.5	40 mg	30 mg
9.0	75 mg	55 mg
13.6	115 mg	85 mg
18.1	150 mg	115 mg
22.7	190 mg	140 mg
Weight in kg	**50 mg/kg/day divided in 3 doses (approx. single dose: mg/every 8 h)**	**50 mg/kg/day divided in 4 doses (approx. single dose: mg/every 6 h)**
4.5	75 mg	55 mg
9.0	150 mg	110 mg
13.6	225 mg	170 mg
18.1	300 mg	225 mg
22.7	375 mg	285 mg

Dosage adjustment in children with renal failure (guidelines):

In children with mild to moderate renal impairment (creatinine clearance of 70 to 40 ml/min), 60% of the normal daily dose given in equally divided doses every 12 hours should be sufficient.

In children with moderate impairment (creatinine clearance of 40 to 20 ml/min), 25% of the normal daily dose given in equally divided doses every 12 hours should be sufficient.

In children with severe impairment (creatinine clearance of 20 to 5 ml/min), 10% of the normal daily dose given every 24 hours should be adequate.

All dose recommendations apply after an initial loading dose is administered.

Perioperative prophylactic use:

To prevent postoperative infection in contaminated or potentially contaminated surgery the recommend doses are:

- 1 g I.V. or I.M. administered half an hour to one hour prior to initiation of surgery.
- for lengthy operative procedures (2 hours or longer) 0.5-1.0 g I.V. or I.M. during surgery (administration modified according to the duration of the operative procedure).
- 0.5 to 1.0 g I.V. or I.M. administered every 6 to 8 hours for 24 hours postoperatively.

If exposure to infections organisms is likely, cefazolin should be administered at appropriate intervals during surgery to provide sufficient levels of antibiotic.

If surgery in which infection may be particularly devastating (open heart surgery and prosthetic arthroplasty), the prophylactic administration of cefazolin may be continued for 3 to 5 days after the completion of surgery. In other cases, prophylactic administration should usually be discontinued within 24h after the surgical procedure, because of risks of adverse reactions.

If there are signs of infection, specimens for culture should be obtained for identification of the causative organisms so that appropriate therapy may be initiated.

Method of Administration:

Parenteral drug should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

I.V. administration:

I.V. administration: Cefazolin may be given either as a direct I.V. injection or as a continuous or intermittent I.V. infusion.

Intravenous injection: Reconstitute 1 g cefazolin with 5 ml-10 ml Water for Injection. The resulting solution must be injected slowly over a period of 3-5 minutes and it may be administered directly into the vein or through tubing.

Intravenous infusion: The administration can be continuous or intermittent. In intermittent intravenous infusion cefazolin can be administered along with primary intravenous fluid management programs in a volume-control set or in a separate secondary I.V. container.

Reconstituted 1 g cefazolin vial may be diluted in 50-100 ml of one of the following intravenous solutions: 0.9% Sodium Chloride Injection, 5% or 10% Dextrose Solution, 5% Dextrose in Lactated Ringer's Injection, 5% Dextrose and 0.9% Sodium Chloride Injection (also may be used with 5% Dextrose and 0.45% or 0.2% Sodium Chloride Injection), Lactated Ringer's Injection, 5% or 10% Invert Sugar in Water for Injection, Ringer's Injections.

I.M. administration:

Cefazolin can be given by deep intramuscular injection.

Do not use in children less than 30 months old (solvent with lidocaine hydrochloride). Dilute cefazolin with the solvent and inject in deep intramuscular injection. Once reconstituted, the solution is stable for 24 hours at ambient temperature. The solution may be yellowish. Use 3 ml of 0.5% lidocaine.

4.3 Contraindications

This medicinal product must not be used in cases of known hypersensitivity to cefazolin or other cephalosporins and in patients who have previously shown immediate and/or severe hypersensitivity reactions to penicillin or to any other beta-lactam antibiotic.

For use in children of less than 30 months of age, cefazolin must not be dissolved in lidocaine solutions.

- Hypersensitivity to lidocaine (I.M. administration).

4.4 Special warnings and precautions for use

Particular caution is required in patients with an allergic diathesis, with bronchial asthma or hay fever. Prior to administering cefazolin, previous hypersensitivity reactions to other beta-lactams (penicillins or cephalosporins) must be investigated.

In patients exhibiting allergic reactions, the product must be discontinued and appropriate symptomatic therapy instituted. Serious acute hypersensitivity reactions may require adrenaline (epinephrine) and other emergency measures, including oxygen, I.V. fluids, I.V. antihistamines, corticosteroids, pressor amines and airway management, as clinically indicated.

Cross-allergy with other cephalosporins and occasional cross-allergies with penicillins must be borne in mind. In cases of known hypersensitivity to penicillin, cross-allergy with other beta-lactams, e.g., cephalosporins, must be taken into account. Cross-hypersensitivity among beta-lactam antibiotics has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy.

Severe hypersensitivity reactions (anaphylaxis) with occasional fatal outcomes have been reported in patients undergoing treatment with beta-lactam antibiotics (see section 4.8). These reactions are more likely to occur in persons with a history of known hypersensitivity to beta-lactam antibiotics.

In patients with impaired renal function, the dosage and/or dosing frequency must be adjusted to the degree of renal dysfunction (see section 4.2). As with other beta-lactam antibiotics, seizures may occur if inappropriately high doses are administered to patients with impaired renal function.

While cefazolin only rarely causes renal impairment, monitoring of renal function is nonetheless recommended, especially in severely ill patients receiving maximum doses and patients under concomitant treatment with other potentially nephrotoxic medicinal products, such as aminoglycosides or potent diuretics (e.g., furosemide).

As with all cephalosporins, cefazolin should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Coagulation disorders may rarely occur during treatment with cefazolin. At risk are patients with risk factors leading to vitamin K deficiency or affecting other coagulation mechanisms (parenteral nutrition, malnutrition, impaired hepatic and renal function, thrombocytopenia). The same applies to comorbidities (e.g., haemophilia, gastrointestinal ulcers) that can trigger or aggravate haemorrhages. Prothrombin values should therefore be monitored in such cases. If these values are reduced, vitamin K replacement should be given (10 mg/week).

In the event of severe and persistent diarrhoea, antibiotic-associated pseudomembranous colitis should be considered, which can be life-threatening. Cefazolin should therefore be discontinued immediately in such cases and appropriate therapy instituted. Antiperistaltic agents are contraindicated.

During long-term use of cefazolin, non-sensitive pathogens may proliferate. Patients should therefore be carefully monitored. If superinfection occurs, appropriate measures should be taken. Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is a primary cause of "antibiotic-associated colitis."

In patients with hypertension or heart failure, the sodium content of the solution for injection must be taken into account (48 mg per 1 g cefazolin).

Children and adolescents

Cefazolin should not be administered to premature and newborn infants of less than one month of age, as no experience is available and the safety of such use has not been demonstrated.

Athletes should bear in mind that positive results may be obtained in anti-doping tests when cefazolin is dissolved in lidocaine.

Not for intrathecal use.

Prescribing cefazolin in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

4.5 Interactions with other medicinal products and other forms of interaction

Concomitant administration contraindicated

Antibiotics

Cefazolin must not be administered together with antibiotics with bacteriostatic activity (e.g., tetracyclines, sulphonamides, erythromycin, chloramphenicol), as antagonistic effects have been observed during *in vitro* tests.

Concomitant administration not recommended

Probenecid

Renal clearance of cefazolin is reduced when probenecid is co-administered.

Precautions

Vitamin K1

Some cephalosporins, such as cefamandole, cefazolin and cefotetan, may interfere with the metabolisation of vitamin K1, particularly in cases of vitamin K1 deficiency. Substitution of vitamin K1 may therefore be necessary.

Anticoagulants

Cephalosporins may, in very rare cases, lead to coagulation disorders (see section 4.4). If oral anticoagulants or high heparin doses are adjuvantly administered, coagulation values must be monitored.

Nephrotoxic substances

It cannot be ruled out that the nephrotoxic effect of antibiotics (e.g., aminoglycosides, colistin, polymyxin B) and diuretics (e.g., furosemide) may be aggravated. If co-administered with cefazolin, renal function tests should be carefully monitored.

Laboratory tests

Laboratory tests may give a false-positive response for urine glucose if Benedict's solution, Fehling's solution or Clinitest® tablets are used, but not when enzyme-based detection methods are applied.

The indirect and direct Coombs' test can also give false-positive results. This may also apply to newborn infants whose mothers have been receiving cephalosporins.

Oral contraceptives

Cefazolin may influence the efficacy of hormonal contraceptives. For this reason, use of additional birth control methods besides hormonal contraceptives is recommended during a course of treatment with cefazolin.

4.6 Fertility, pregnancy and lactation

Pregnancy

To date, there is insufficient experience for the use of cefazolin during human pregnancy.

Hence, cefazolin should only be used during pregnancy after careful benefit/risk assessment.

This applies particularly to the first trimester. Cefazolin crosses the placenta.

Lactation

Cefazolin is excreted in human milk at low concentrations. In breast-fed infants, sensitisation and changes in the intestinal flora and *Candida* infections may occur. In these cases, breast-feeding should be suspended during treatment.

4.7 Effects on ability to drive and use machines

Cefazolin has no influence or negligible influence on the ability to drive and use machines.

However, some adverse reactions (e.g., vertigo, headache, paraesthesia, agitation, seizures; see section 4.8) may affect the ability to concentrate and reaction times and may therefore impair the ability to drive or use machines.

4.8 Undesirable effects

The undesirable effects are categorised as follows:

Very common: ≥ 1/10
Common: ≥ 1/100 to < 1/10
Uncommon: ≥ 1/1,000 to <1/100
Rare: ≥1/10,000 to <1/1,000
Very rare: < 1/10,000.
Not known: cannot be estimated from the available data

System organ classes	Common	Uncommon	Rare	Very rare	Not known
Infections and infestations					Long-term treatment or repeated use can lead to superinfections or colonisation with resistant bacteria or yeast-like fungi (oral thrush, vaginal candidiasis)
Blood and lymphatic system disorders		Thrombocytopenia, neutropenia, leukopenia, eosinophilia, agranulocytosis, haemolytic anaemia	Coagulation disorders, haemorrhages*		Leukocytosis, granulocytosis, monocytosis, lymphocytopenia, basophilia, reduced haemoglobin and/or haematocrit, aplastic anaemia, pancytopenia
Immune system disorders	Allergic skin reactions such as erythema, generalized exanthema, urticaria and pruritus	Serious hypersensitivity reactions such as angioderma and drug fever		Life-threatening anaphylactic shock**	Erythema exsudativum multiforme, interstitial pneumonia or pneumonitis, Lyell's syndrome, Stevens-Johnson syndrome
Nervous system disorders					Headache, dizziness, malaise, tiredness, vertigo, paraesthesia, excitation of the central nervous system, hyperactivity, nervousness or anxiety, sleeplessness, sleepiness, weakness, hot flushes, colour perception changes and confused states, myoclonus, seizures[a], convulsive fits[a], aseptic meningitis
Gastrointestinal disorders	Diarrhoea, nausea, loss of appetite, flatulence, abdominal pain[b]				Pseudomembranous colitis[c]
Hepatobiliary disorders		Mild, transient elevation of AST, ALT and alkaline phosphatase		Reversible hepatitis and cholestatic jaundice	Raised GGT, bilirubin and/or LDH
Renal and urinary disorders			Interstitial nephritis and other renal disorders[d]		Transient rise in BUN levels (blood, urea, nitrogen) and serum creatinine concentrations, nephrotoxicity[d]
General disorders and administration site conditions		Phlebitis, thrombophlebitis			Chest pains, pleural effusion, dyspnoea or respiratory distress, cough, rhinitis, raised or lowered serum glucose concentration, genital and anal pruritus, genital moniliasis, vaginitis, pain from I.M. administration. Photosensitive phenomena have been described.

* At risk are patients with risk factors leading to vitamin K deficiency or affecting other coagulation mechanisms as well as patients with disorders that can trigger or aggravate haemorrhages.
** Symptom which may require appropriate immediate emergency measures.
[a] Particularly in the event of an overdose or unadjusted dosage in patients with renal impairment.
[b] In most cases, the symptoms are mild in nature and often resolve, if not during, then after discontinuation of treatment.
[c] In the event of severe and persistent diarrhoea during or after treatment with cefazolin, a doctor must be consulted, as this may be a sign of a severe condition (pseudomembranous colitis), which must be treated immediately (e.g., with vancomycin oral 250 mg 4 times daily). The patient must refrain from all self-medication with antiperistaltic agents.
[d] Mostly occurring in severely ill patients receiving several medicinal products.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:
https://sideeffects.health.gov.il

4.9 Overdose

Symptoms of overdose:

An overdose can cause pain, inflammatory reactions and phlebitis at the injection site. Administration of very high parenteral cephalosporin doses can result in vertigo, paraesthesia, and headache. Particularly in patients with renal disease, seizures may occur following an overdose with cephalosporins.

The following abnormal laboratory test results may occur after an overdose: elevated creatinine values, BUN, liver enzyme values and bilirubin; positive Coombs' test; thrombocytosis and thrombocytopenia, eosinophilia, leukopenia and prolongation of the prothrombin time.

Treatment of an overdose:

If seizures occur, the product must be discontinued immediately. Treatment with anticonvulsants may be indicated. Vital body functions and relevant laboratory parameters must be very carefully monitored. In the event of a severe overdose, a combination of haemodialysis and haemoperfusion may be beneficial if other treatments are unsuccessful, although supportive data to this are lacking. Peritoneal dialysis is ineffective.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: other beta-lactam antibiotics, 1st-generation cephalosporins.

ATC code: J01DB04

Mode of action

The mechanism of action of cefazolin is based on inhibition of bacterial cell wall synthesis (in the growth phase), due to blockade of penicillin-binding proteins (PBPs), e.g., transpeptidases. This results in a bactericidal action.

Pharmacokinetic/pharmacodynamic relationship

Efficacy largely depends on the length of time during which the active substance level remains above the minimum inhibitory concentration (MIC) of the pathogen.

Resistance mechanisms

Resistance to cefazolin can be due to the following mechanisms:

- Inactivation by beta-lactamases: cefazolin is largely stable against penicillinases of Gram-positive bacteria, although it has only low stability against numerous plasmid-encoded beta-lactamases, e.g., extended-spectrum beta-lactamases (ESBLs) or chromosome-encoded beta-lactamases of the AmpC type.
- Reduced affinity of PBPs to cefazolin: acquired resistance in pneumococci and other streptococci is due to modifications of PBPs present as a result of a mutation.
  However, the formation of an additional PBP with reduced affinity for cefazolin is responsible for resistance in methicillin (oxacillin)-resistant staphylococci.
- In Gram-negative bacteria, insufficient penetration of cefazolin through the outer cell wall can lead to insufficient PBP inhibition.
- Cefazolin can be actively transported from the cell by efflux pumps.

Cefazolin is partially or completely cross-resistant with other cephalosporins and penicillins.

Breakpoints

Cefazolin is tested using the standard dilution series. The following minimum inhibitory concentrations for susceptible and resistant germs have been established:

EUCAST (European Committee on Antimicrobial Susceptibility Testing) breakpoints (2011-01-05, version 1.3):

Pathogen	Susceptibility	Resistance
Staphylococcus spp.	--*	--*
Streptococcus groups A, B, C, G	--**	--**
Other streptococci [a]	≤ 0.5 mg/l	> 0.5 mg/l
Non-species-specific breakpoints	1 mg/l	> 2 mg/l

* Susceptibility of staphylococci to cefazolin can be derived from their susceptibility to cefoxitin.
** Beta-lactam susceptibility of groups A, B, C and G beta-haemolytic streptococci can be derived from their susceptibility to penicillin.
[a] For endocarditis, see national or international endocarditis guidelines for *Streptococcus viridans* breakpoints.

Susceptibility

For individual species, the prevalence of acquired resistance may vary geographically and over time. Therefore, local information on the resistance situation is required, particularly for the adequate treatment of severe infections. If, based on the local resistance situation, the efficacy of cefazolin is questionable, expert therapeutic advice should be sought.

Usually susceptible species
Gram-positive aerobes
Staphylococcus aureus (methicillin-sensitive)°
Staphylococcus saprophyticus°
Streptococcus agalactiae°
Streptococcus pneumoniae
Streptococcus pyogenes°
Species, in which acquired resistance may pose a problem during use
Gram-positive aerobes
Staphylococcus aureus[3]
Staphylococcus epidermidis[+]
Staphylococcus haemolyticus[+]
Staphylococcus hominis[+]
Staphylococcus pneumoniae (penicillin-intermediate)
Gram-negative aerobes
Escherichia coli
Haemophilus influenzae[$]
Klebsiella oxytoca[∞]
Klebsiella pneumoniae
Proteus mirabilis
Naturally-resistant species
Gram-positive aerobes
Enterococcus spp.
Staphylococcus aureus (methicillin-sensitive)
Staphylococcus pneumoniae (penicillin-resistant)
Gram-negative aerobes
Acinetobacter baumannii
Citrobacter freundii
Enterobacter spp.
Morganella morganii
Moraxella catarrhalis
Proteus vulgaris
Pseudomonas aeruginosa
Serratia marcescens
Stenotrophomonas maltophilia
Anaerobes
Bacteroides fragilis
Other micro-organisms
Chlamydia spp.
Chlamydophila spp.
Legionella spp.
Mycoplasma spp.

° Susceptibility is assumed in the primary literature, standard works and therapeutic recommendations.
[$] Natural susceptibility of most isolates lies within the intermediate range.
[+] The rate of resistance is over 50% in at least one region.
[∞] No current data available; in studies (more than 5 years old), the proportion of resistant strains is stated to be > 50%.
[3] Outside the hospital setting, the resistance rate is < 10%.

Further information

Penicillin-resistant *Streptococcus pneumoniae* is cross-resistant to cephalosporins such as cefazolin.

5.2 Pharmacokinetic properties

Cefazolin is administered parenterally. Peak plasma levels are reached after I.M. injection within 30 to 75 minutes.

Plasma concentrations (µg/ml) after intramuscular administration						
Dose	30 min	1 h	2 h	4 h	6 h	8 h
500 mg	36.2	36.8	37.9	15.5	6.3	3.0
1 g	60.1	63.8	54.3	29.3	13.2	7.1
Plasma concentrations (µg/ml) after intravenous administration of 1 g						
	5 min	15 min	30 min	1 h	2 h	4 h
	188.4	135.8	106.8	73.7	45.6	16.5

Approximately 65-92% of cefazolin is bound to plasma proteins. Cefazolin has good penetration into tissue such as skeletal muscles, myocardium, bone, bile and gallbladder, endometrium and vagina. Cefazolin penetrates the placental barrier and is also excreted in human milk. Diffusion into cerebrospinal fluid and aqueous humour is inadequate.

Cefazolin is not metabolised. It is excreted in the microbiologically active form mainly via the kidneys by means of glomerular filtration. A small moiety is excreted via the bile. The plasma elimination half-life is approximately two hours; in patients with renal insufficiency, the plasma half-life may be prolonged.

5.3 Preclinical safety data

Repeated administration of cefazolin to dogs and rats using different routes of injection over a period of one to six months showed no significant effects on biochemical and haematological values. Signs of neurotoxicity were seen in some studies.

After I.M. injection, cefazolin is only poorly tolerated at the injection site.

In studies on rabbits, the kidney appeared to be the target organ, though not in rats and dogs.

Cefazolin showed no teratogenic activity and did not affect general reproductive functions.

No studies are available concerning mutagenicity and carcinogenicity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cefazolin does not contain any excipients.

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 4.2.

6.3 Shelf life

24 months

6.4 Storage

Store below 25°C, protected from light in its original package.

For I.M. route: the drug product should be reconstituted with 3 ml in Water for Injection or in lidocaine 0.5%.

For I.V. route: the drug product should be reconstituted in 5-10 ml in Water for Injection, Glucose 5% or NaCl 0.9%.

After reconstitution:

Reconstituted 1 gm cefazolin vial may be diluted in 50-100 ml of one of the following intravenous solutions: 0.9% Sodium Chloride Injection, 5% or 10% Dextrose Solution, 5% Dextrose in Lactated Ringer's Injection, 5% and 0.9% Sodium Chloride Injection (also may be used with 5% Dextrose and 0.45% or 0.2% Sodium Chloride Injection), Lactated Ringer's Injection.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C, unless dilution has taken place in controlled and validated aseptic conditions.

6.5 Nature and content of container

Cefazolin Panpharma 1 g of powder in a vial (glass); box of 25

6.6 Special precautions for handling and removal

No special requirements.

7. MANUFACTURER:

PANPHARMA
Z.I. du Clairay – 35133, Luitré,
FRANCE

8. LICENSE HOLDER AND IMPORTER:

Pharmalogic LTD., 14 Imber St., Petah-Tikva 49511.

9. REGISTRATION NO.:

149 28 33854 00
149 28 33854 01

The content of this leaflet was approved by the Ministry of Health in February 2013 and updated according to the guidelines of the Ministry of Health in June 2019.